TAHC – September 2007 Report
**USA Comments**

## Chapter 2.3.13
## Bovine Spongiform Encephalopathy

**Comment on the recent deliberations**

In the report of the March 12-16, 2007 meeting of the OIE Terrestrial Animal Health Standards Commission regarding the trade of gelatin, the Code Commission proposed that all gelatin, as well as dicalcium phosphate produced in the manufacturing of gelatin, irrespective of the raw material from which it is made, be included in Article 2.3.13.1, the article listing those commodities which can be traded without regard to the BSE status of the country. At that time, in its report, the Commission set forth the scientific studies and risk assessments which justified this position.

However, in May of 2007, the Commission withdrew this proposal with no scientific justification being provided for such action. With this proposal withdrawn, the Commission recommended that the 2006 Edition of the *Code* stand.

Most recently, at its September 2007 meeting the Commission again recommended amending the BSE *Code* Chapter. This most recent recommendation appears to be the Commission's first step toward making the *Code* (with respect to gelatin) consistent with the results of extensive scientific studies and risk assessments. While it is an incremental step, it is still neither transparent nor technically evident given the current environment under which the BSE issue is managed. Considering the important role of the OIE as the international standard setting body for animal health, it is critical that it adhere to the use of science-based information upon which to base its recommendations.

**Recommended changes to Chapter 2.3.13**

The United States has recommended (supported with scientific documentation) that Article 2.3.13.14 be deleted from the *Code* and that Article 2.3.13.1 be modified to reflect that all gelatin, as well as bone chips and ossein utilized in gelatin production and dicalcium phosphate obtained from the processing of gelatin, be freely traded without regard to the BSE risk status of the cattle population.

These recommended changes with extensive scientific documentation have been previously submitted to the OIE by the US Delegate. For the convenience of the Commission, these are again being submitted and can be found as an attachment (Annex A) to this document.

**Specific Comments to the proposed Code Chapter Changes found in the September 2007 Report**

The Code Commission recognizes that changes need to be made to the 2007 *Code* with regard to gelatin and its by-product, dicalcium phosphate, if the *Code* is to reflect the current status of scientific understanding. While the science to support the removal of any BSE-related restrictions on the trade of gelatin and its by-products is available (see Annex A), we recognize that the OIE may be approaching this goal with incremental steps.

Accordingly, the United States, for now, will support the addition of Article 2.3.13.16 *bis* to Chapter 2.3.13 (and the associated deletions in Article 2.3.13.16) wherein it is being recommended that dicalcium phosphate can be safely imported from countries with negligible BSE risk and from countries posing controlled or undetermined BSE risk if it is a by-product of bone gelatin produced according to Article 2.3.13.15.

Further, the United States will support, as an incremental step forward, the combining of bone sourcing and processing steps required of countries posing a controlled or undetermined BSE risk. However, the United States believes that the OIE, in proceeding in this stepwise manner, is not promoting its goal of having all countries be categorized in the OIE three category system. Specifically, by having the same requirements for the trade of gelatin from countries posing an undetermined BSE risk as that from countries with controlled BSE risk provides no incentive for countries of undetermined risk to undergo the OIE evaluation and categorization process.

We believe that if the OIE is moving with stepwise changes to the Code Chapter on BSE, and which will ultimately result in gelatin, as well as bone chips and ossein utilized in gelatin production and dicalcium phosphate obtained from the processing of gelatin, being included in Article 2.3.13.1, then the most logical step to take at this point in time is to combine the requirements for bone gelatin originating in countries with negligible risk and controlled risk status. By definition, controlled risk countries have demonstrated that they have taken the necessary measures to mitigate any potential BSE, have put into place effective management processes, and have surveillance systems to monitor this effectiveness. Countries having controlled BSE risk status are much more like countries with negligible BSE risk status than like those with undetermined BSE risk status.

International standards must be developed according to the country status with respect to the disease, the science currently available, and the outcome of risk assessments. The United States has presented sound and well grounded scientific evidence so that there should be no justifiable scientific reason to prevent the free trade of gelatin, as well as bone chips and ossein utilized in gelatin production and dicalcium phosphate obtained from the processing of gelatin.

# Annex A

# OIE Code Chapter on Bovine Spongiform Encephalopathy
# Chapter 2.3.13

**Terrestrial Animal Health Standards Commission Report – October 2006**
**USA Comments**

**General Comment to proposed changes to Article 2.3.13.14 (re: Gelatin and Collagen):**

The United States supports the removal of the requirement to exclude skulls and vertebrae from raw material used in the production of gelatin for zones posing a controlled or undetermined risk. We agree that such a decision is firmly grounded in science as demonstrated by the opinion of the scientific panel on biological hazards of the European Food Safety Authority (EFSA) wherein it is stated that the exclusion of skulls and vertebrae does not significantly contribute to the safety of gelatin.[1]

That said, however, we believe that Article 2.3.13.14. should be deleted in its entirety and that ALL gelatin, irrespective of the raw material from which it is made, can be included in Article 2.3.13.1, commodities which can be traded without regard to the BSE risk status of the cattle population, as explained and documented below.

**Suggested changes:**

**Article 2.3.13.1**

…

1. When authorizing import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone*, or *compartment:*

    a) *milk* and *milk products;*

[1] European Food Safety Authority Journal 2006 312 (1-28).

b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

c) hides and skins;

d) gelatine and ~~collagen~~ prepared ~~exclusively~~ from hides~~, and~~ skins or bones;

e) collagen prepared exclusively from hides and skins;

f) degreased bone chips and ossein (demineralised bone) utilized for gelatine production;

g) dicalcium phosphate obtained from the processing of ossein or bovine bone gelatine (with ~~no trace of protein or fat~~ less than 0.5% protein);

h) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;

i) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

**Rationale (for the addition of gelatine prepared from bones):**

The Terrestrial Code Commission received and considered "Supporting Documentation for Chapter 2.3.13 of the Terrestrial Animal Health Code on BSE." This report referenced the opinion of the scientific panel on biological hazards of the EFSA which indicates that ". . . relative human exposures to BSE due to gelatin produced from bones including the skull and vertebral column sourced from cattle of any age are very low ($<10^{-5}$) and do not support the continuation of the restriction prohibiting the inclusion of skull and vertebral column."[2]

However, this report states that the EFSA risk assessment did not consider the risk of sourcing bones from animals other than those deemed fit for human consumption and, therefore, those passing ante-mortem and post-mortem inspections. Further, this report

[2] Appendix XXVIII of the report of the meeting of the OIE Terrestrial Animal Health Standards Commission 2-13 October 2006.

indicates that to be consistent with the conservative approach adopted with respect to BSE, the commercial process for gelatin production must have been correctly carried out.

We believe these two restrictions are neither appropriate nor needed to ensure the safe supply of gelatin. Extensive research studies conducted by credible and independent scientists, and published in peer-reviewed research journals have demonstrated that the common process of manufacturing bovine gelatin provides significant assurance of gelatin safety. Specifically, studies have shown current minimum processes that all manufacturers have in common (and that technically must be utilized to produce a marketable product) are more than sufficient to eliminate BSE infectivity from "worst case" artificially contaminated raw materials. This "worst case" infectivity of $10^{8.4}$ is far more than that found in raw materials sourced in the country which had the highest incidence of BSE at the height of the BSE epidemic.[3] [4] [5] Gelatin is a high-purity protein manufactured through various refining processes in which each step of processing is capable of significantly inactivating BSE infectivity.

The New Zealand Food Safety Authority has proven through carefully conducted risk assessments the safety of gelatin beyond reasonable doubt regardless of the BSE status of source countries.[6] Given this document, the fact that BSE is very much in decline and certainly the epidemic is well under control, and that the Terrestrial Code Commission is grounded in basing all decisions on science-based information, the United States, therefore, requests that all gelatin should be freely traded regardless of the BSE risk status of the cattle population.

**Rationale (for the addition of degreased bone chips and ossein):**

Even with the inclusion of ALL gelatin in Article 2.3.13.1, commodities that can be traded without any BSE related conditions regardless of the BSE risk status of the cattle population international trade will still be impeded due to restrictions placed on the immediate commodity, degreased bone chips, used exclusively in the manufacture of gelatin.

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[3] Grobben AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatin. *Biotechnology and Applied Biochemistry*, 39; 329-338.

[4] Grobben AH, Steel PJ, Taylor DM, Somerville RA, Schreuder BEC (2005). Inactivation of the BSE agent by heat and pressure process for manufacturing gelatin. *Veterinary Record*, 157; 277-289.

[5] Grobben AH, Steele PH, Somerville RA, Taylor DM (2006). Inactivation of transmissible spongiform encephalopathy agents during the manufacture of dicalcium phosphate from bone. *Veterinary Record*, 158; 361-366.

[6] NZFSA (2005). Official's Review of New Zealand's BSE Country-Categorisation Measure. New Zealand Food Safety Authority, Wellington and published in "prions in Humans and Animals, Ed. By Hornlimann, Beat/ Riesner, Detlv / Kretzschmar, Hans. De Gruyter Veriag, Berlin (ISBN 978-3-11-018275-0).

Bone itself is free from BSE infectivity. The finding of infectivity in bone marrow, on one occasion, is now being questioned as a procedural error by OIE.[7]

Before bones can be used in the manufacture of gelatin, fat and other impurities must be removed by a process called "degreasing". The bones are crushed to a size of less than 12 mm and then washed and degreased in a process that removes any residues of fat, marrow or other soft tissues.

Studies evaluating the effectiveness of the degreasing process for removing nervous tissue proteins from bones have demonstrated that degreasing eliminates 98% to 99% of such proteins.[8] It has been shown that the degreasing process alone reduces any BSE contamination of bone by a factor of approximately $10^2$.[9]

When degreased bone chips are used to manufacture gelatin, there is no direct exposure of BSE infectivity (even if such were present). Therefore, the United States requests that degreased bone chips used in the production of gelatin should be traded without any BSE related conditions regardless of the BSE risk status of the cattle population.

**For ossein:**

Before degreased bone chip material can be utilized to produce gelatin, it must have the minerals present, including calcium and phosphate, removed from it. This is accomplished by soaking the bone chip in hydrochloric acid (approximately 4%, <pH 1.5) for a period of at least 2 days. The resultant demineralized collagen is known as ossein. Ossein is the component which undergoes further processing and purification and becomes gelatin. Ossein is a commodity for which there is international trade demand.

Research by Grobben et al. has proven that this hydrochloric acid treatment significantly reduces any BSE infectivity, if such might be present. This reduction is cumulative to that accomplished by the bone chip degreasing process.[10]

Ossein is used exclusively in the manufacture of gelatin. Therefore, there can be no direct exposure of BSE infectivity from ossein, even if in the unlikely circumstance that it were present. Based on these research findings, ossein can be traded without any BSE related conditions regardless of the BSE risk status of the cattle population.

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[7] OIE Terrestrial Animal Health Standards Commission/October 2006, Appendix XXVIII.

[8] Manzke U, Schlaf G, Poethke R, Felgenhauer K, Mader M (1996). On the removal of nervous proteins from materials used for gelatine manufacturing during processing. *Pharmazeutische Industrie,* 58 (9); 837-841.

[9] Pharmaceutical Research and Manufactures of America BSE Committee (1998). Assessment of the risk of bovine spongiform encephalopathy in pharmaceutical products. *BioPharm*, 11 (3); 18-30.

[10] Grobben AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatin. *Biotechnology and Applied Biochemistry,* 39; 329-338.

**d. Rationale (to amend trade conditions for dicalcium phosphate):**

Considerable mineral content is recovered from the hydrochloric acid treatment of bone chip used in the production of gelatin. These recovered minerals are further purified, followed by precipitation and drying. The resultant product is dicalcium phosphate.

Raw materials for bone gelatin production originate from healthy slaughtered cattle found fit for human consumption following ante-mortem and post-mortem inspections. The same processing steps applied for the pre-treatment of bones used to produce bone gelatin are followed for pre-treatment of bones for the production of dicalcium phosphate.

Accordingly, studies which demonstrate the safety of gelatin resulting from the pre-treatment of bone during degreasing and acid demineralization[11] also indicate that a very safe dicalcium phosphate is yielded as a by product of the gelatin manufacturing process. Further, a significant reduction of TSE infectivity under experimental conditions has been demonstrated for dicalcium phosphate by a recent validation study.[12]

[11] Grobben Ah, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine. *Biotechnology and Applied Biochemistry,* 39; 329-338.

[12] Grobben AH, Steele PJ, Somerville RA, Taylor DM (2006). Inactivation of transmissible spongiform encephalopaghy agents during the manufacture of dicalcium phosphate from bone. *Veterinary Record,* 158; 361-366.